Premarket Notification [510(k)] Summary

(per 21 CFR 807.92)

1. Submitted by:

Nu Photonics, Inc.
P.O. Box 22599
Denver, CO 80222

Contact Person: William Michael Brock
Chairman of the Board
Telephone: 303-922-9200
Facsimile: 303-922-9800

Date Prepared: August 24, 2001

2. Device Name

Trade/Proprietary Name: Nu Photonics Pain Therapist
Common/Usual Name: Infrared heat lamp
Classification Name: Infrared lamp (per 21 CFR 890.5500)

3. Predicate Device:

The Nu Photonics Pain Therapist is substantially equivalent to other infrared lamps on the market, such as the Acubeam system manufactured by Light Force Therapy, Inc., the Light Patch manufactured by BioScan, Inc., the Photonic Stimulator manufactured by Bales Scientific, Inc., and the Pain-X 2000, manufactured by Diomedics, Inc.

4. Intended use of the device

This infrared heat lamp is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature. This unit may be used to provide temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm. This unit may temporarily increase local blood circulation, and may be used to promote relaxation of the muscle tissue.

5. Description of the Device

The Nu Photonics Pain Therapist consists of a collection of both infrared and red diodes packaged in a compact plastic case. The system emits pulsed light in the infrared spectrum to provide topical heating, arranged in an area covering just

over 11 square inches. The red diodes provide a visible indication that the unit is in operation.

The system incorporates an "Auto Off" feature, in the event that the user may inadvertently leave the device on.

6. Summary of the technological characteristics of the device compared to the predicate device.

The Nu Photonics Pain Therapist and the above referenced predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared diodes to provide topical heating for the temporary relief of muscle and/or joint pain. The temperatures achieved by these devices are the same, using a similar number of diodes over a similar coverage area. The devices are handheld, and intended to be placed directly on the skin or held just over the skin to provide the heating.

7. Testing

Testing of the Nu Photonics Pain Therapist included functional performance testing and electrical leakage testing.

8. Conclusions

Based upon the testing and comparison to the predicate devices, the Nu Photonics Pain Therapist has the same intended uses, with similar technological characteristics. The system performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 9 2001

Nu Photonics, Inc.
c/o Entela, Inc.
Ned Devine, Program Manager III
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K012508
Trade/Device Name: Nu Photonics Pain Therapist
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: August 31, 2001
Received: September 28, 2001

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

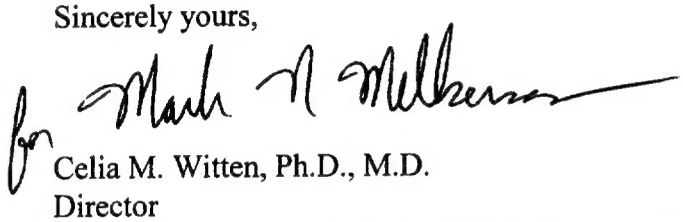
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K 012508

Device Name: Nu Photonics Pain Therapist

Indications for Use:

This infrared heat lamp is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature. This unit may be used to provide temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm. This unit may temporarily increase local blood circulation, and may be used to promote relaxation of the muscle tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: (per 21 CFR 801.109) OR Over the Counter Use: (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K012508